

**REMARKS**

**A Request for a Two (2) Month Extension of Time pursuant to 37 CFR §1.136(a) and (b) is attached hereto.**

The above-captioned patent application has again been carefully reviewed in light of the final Office Action to which this Amendment is responsive. Claims 1, 4, 6-12 and 74-76 have been amended in an effort to further clarify and distinctly describe the combination claimed herein. Claims 3, 13, 14, 77 and 78 have been canceled.

Claims 1, 3, 4, 6-14 and 74-78 are pending. Each of the pending claims have been rejected in light of certain prior art. More particularly, Claims 1, 3, 4, 6-14 and 74-78 have been rejected under 35 USC §103(a) based on the combination of Jacobs et al. (U.S. Patent No. 5,846,492) in view of Corbett (WO 92/20778) and/or Samssoondar (WO 99/47261). Claims 1, 3, 4, 6-14 and 74-78 have also been rejected under 35 USC §103(a) based solely on Jacobs et al. (U.S. Patent No. 6,797,518). Claims 1, 3, 4, 6-14 and 74-78 have also been rejected under 35 USC §103(a) based on the combination of Jacobs et al. '518 and Samssoondar.

All pending Claims 1, 3, 4, 6-14 and 74-78 have also been rejected under 35 USC §112, 2<sup>nd</sup> paragraph, for indefiniteness issues. Applicant respectfully requests reconsideration based on the amended claims, as well as the following discussion.

Applicant would like to gratefully acknowledge the telephonic interview granted by Examiner Jan Ludlow to Applicant's representative, Peter J. Bilinski, on April 12, 2007. The subject matter of that interview is provided herein in this correspondence.

With regard to the prior art rejections, it is previously been noted that in order to successfully maintain a "*prima facie*" obviousness rejection under the Statute, each and every claimed limitation must be found in or suggested by the prior art. Those limitations that are neither found in the prior art nor suggested thereby must be notoriously well known at the time of the invention to those of ordinary skill, in the field of the invention. In terms of combining references, there must also be a motivation found in the prior art as a whole in order to make the purported combination. This

combination cannot be through advance knowledge (i.e., hindsight) of the present invention.

Applicant has amended independent Claim 1 to now more clearly recite and define the herein auxiliary sample handler by reciting positive structural features thereof in an effort to better clarify and distinctly point out that which is regarded as the present invention. More specifically, this claim has been amended to now specify a housing that includes a plurality of tip retaining stations as well as a housing cover sized to cover each of the tip retaining stations. A drive mechanism is used to rotate the tip retaining stations about an axis of rotation. A plurality of metering tips are also provided that are disposed in the plurality of tip retaining stations, the tips having a dispense end and configured to contain a quantity of patient sample that has been obtained from a primary sample supply of a clinical analyzer. A sealing mechanism is disposed on the housing to seals the dispense end of each of the metering tips as well as a tip stripping mechanism that is disposed on the housing cover that permits each sealed metering tip, now forming a secondary sample container, to be removed from a metering mechanism of the clinical analyzer. The auxiliary sample handler, as now positively recited according to amended Claim 1, further includes an aspiration station including an opening in the housing cover, the latter permitting access by a metering mechanism for purposes of aspirating sample liquid from the tip, as needed. Support is provided for each of the foregoing amendments. See, for example, page 11, line 10- page 12, line 4, and page16, lines 7-18, as well as Figs. 2, 3, 5 and 6. Therefore, it is believed no new matter has been added. Dependent Claims 3, 13, 14, 77 and 78 have been canceled.

It is believed the foregoing claim amendments clearly distinguish Claim 1 from the cited prior art. Jacobs '492 provides a teaching of conventional so-called "dry slide" clinical analyzers, in which the analyzer is further equipped for "through the tip" optical sample analyzers. As noted above, Claim 1, as amended, now includes a plurality of sealed tips and a plurality of tip retaining stations for the tips. This claim further includes a tip sealing mechanism in the housing, as well as a housing cover that

includes a tip stripping mechanism as well as an aspiration station. It is believed that Jacobs '492 fails to teach, recite or otherwise suggest inclusion of the above features.

Turning to the secondary cited references, Corbett illustrates a device used for reaction control in conjunction with polymerized chain reaction (PCR) testing. This device includes an incubator having concentric rings in which a plurality of outer wells receive pipette tips and samples are contained in the pipette tips by sealing a lower end of the tip. This reference utilizes the sample tip as a reaction vessel wherein the incubator is used to heat and/or cool the tips containing sample. As noted in this reference "...there is no transfer of sample to a sample container for reaction". As such, the sealed disposable tips described by Corbett are not utilized as an auxiliary sample holder, but rather are treated no differently than any reaction vessel, such as, for example, a dry slide element as described by Jacobs et al. '492. Sample is not removed from the tip for other purposes, such as for aspirating purposes in conjunction with a second chemistry system of the analyzer.

Samsoondar describes a method and process by which "through the tip" optical measurements can be made using a disposable metering tip. In this disclosure, the tip is sealed by means that are not shown and it is further observed that the tip can receive reagents using a second tip that is capable of being inserted into the first sealed tip "for adding one or more reagents to the disposable metering tip". Following receipt of all of the above-noted fluids, the tip is placed in relation to a radiation source that is sensed to correlate the concentrations of one or more proteins in the sample. As such, the sealed metering tip is simply used a reaction vessel. No teaching is provided or suggested that the sealed metering tip can be utilized as an auxiliary sample container and therefore used in lieu of the primary sample containers of the analyzer.

Nowhere does any of Jacobs '492, Corbett and/or Samsoondar, alone or in combination, teach or describe the above features nor is there any suggestion to provide such teachings. In fact, reading the cited references in their entirety, as is required, would provide a contrary teaching in that Corbett and Samsoondar each require that the sealed tips be utilized only as reaction vessels and not as sample

supplies or containers. As a result, it is believed this rejection of Claim 1 should be withdrawn. Dependent Claims 4, 6-12, and 74-76 should be allowed over these references for the same reasons relating to amended Claim 1.

Discussion is now made concerning the Examiner's rejection of Claims 1, 3, 4, 6-14 and 74-78 based on Jacobs et al. '518, taken alone or in combination with Samsoondar. Jacobs '518 describes the use of "through the tip" optical analysis in a clinical analyzer wherein it is noted briefly (see col. 7, lines 44-52) that a sealed tip may further be used as an auxiliary sample container. Applicant notes, however, that this reference fails to describe all of the salient features of the presently claimed sample handler. That is, the auxiliary sample handler includes a plurality of tip retaining stations within a housing as well as a cover. The cover protects the tips and further includes a tip stripping mechanism that permits a metering tip to be stripped or removed from a metering mechanism, the tip still containing a plurality of sample liquid such that vacuum must continue to be maintained. The sample handler further includes a sealing mechanism that is used to seal each metering tip prior to stripping of same wherein the sealing mechanism permits each dispense end to be sealed to retain the liquid contents of the tip. In addition, the cover still further includes an opening that forms an aspiration station wherein a drive mechanism rotates the housing and each tip retaining station in relation to the aspiration station to permit liquid to be aspirated selectively from a sealed metering tip. None of Jacobs '518 and/or Samsoondar and/or Corbett either describe or suggest the foregoing combination of features, as now positively recited according to amended Claim 1. As a result, it is believed there can be no prima facie case of obviousness under the Statute in that certain essential features are entirely missing from the cited art. Therefore, reconsideration is respectfully requested.

Because independent Claim 1 is now believed to be allowable, we further believe that dependent Claims 4, 6-12 and 74-76 are also patentably distinct from the prior art since none of the above prior art cited by the Examiner includes or suggests all of the features now included in independent Claim 1. Reconsideration is therefore respectfully requested.

As to the Section 112 rejections, we believe the amendments to Claim 1 and its progeny now render this issue as moot. Each of the pending claims of the present application have also been amended to now positively recite the auxiliary sample handler and its salient features. Withdrawal of this rejection is respectfully requested.


In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, she is invited to contact Applicant's representative at the telephone number below.

Applicant herein authorizes the Director to charge our Deposit Account No. 50-0289, under Order No. 961\_006RCE from which the undersigned is authorized to draw for purposes of the two (2) month Extension of Time. If additional fees are required, the Director is further charged to charge the above Deposit Account and to credit any overcharges thereto.

Dated: April 16, 2007

Respectfully submitted,

By 

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